



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *g1373d*

Telephone (973) 526-6009

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

June 8, 2001

**WARNING LETTER**

**CERTIFIED MAIL-**  
**RETURN RECEIPT REQUESTED**

Michael Lutz  
President  
Prosec Security Systems, Inc.  
1985 Swarthmore Avenue  
Lakewood, New Jersey 08701

Dear Mr. Lutz:

**File No.: 01-NWJ-26**

During an inspection of your firm located in Lakewood, New Jersey, on May 10 & 11, 2001, an investigator from the Food and Drug Administration (FDA) determined that you are a manufacturer, repacker and sterilizer of umbilical cord clamps with a security transponder, which are medical devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

This inspection also determined that your firm is not in compliance with applicable regulations concerning medical devices, which renders your medical devices adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) regulations (21CFR, Part 820) for medical devices. The inspection disclosed the following significant violations:

1. Failure to establish and implement a Quality System. For example, there is no documented evidence that you have conducted management reviews and quality audits.
2. Quality system procedures are not yet approved, nor complete for all operations. For example, you do not have written procedures for implementing corrective and preventive actions. You recently recalled the umbilical cord clamp in response to complaints, yet you do not have any documented evaluation of corrective and preventive actions taken, as a result of these complaints.

3. There are no design control procedures in place. For example, as a result of the recent recall, the umbilical cord clamp was re-designed by your supplier, yet you have no documentation that appropriate design controls were applied to the product, including risk analysis, acceptance criteria, design verification and design validation.
4. There is no assurance that the sterilization processes utilizing ethylene oxide and hydrogen peroxide are effective for the product and packaging. For example, you have not conducted any validation studies to determine if the sterilization cycles used are effective in achieving a sterility assurance level of  $10^{-6}$ . You merely rely on a color indicator that shows exposure of the packaging to the sterilizing agent. However, you have not evaluated whether the sterilization process, in fact, sterilizes your product.
5. Failure to establish and monitor environmental conditions. For example, the inspection revealed that your employees used the manufacturing area as a lunchroom. In addition, you have not established or monitored product bioburden levels.
6. There is no documented training program to assure employees have the knowledge and training to adequately perform their assigned duties.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA483 issued to you at the conclusion of the inspection, are symptomatic of serious underlying problems within your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

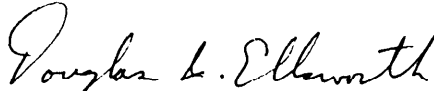
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

We have not yet received a written response to the FDA483 Inspectional Observations issued to you at the conclusion of our inspection. You may wish to check FDA's website at <http://www.fda.gov/cdrh> for guidance in complying with Quality System regulations. Another helpful resource is a book edited by Kimberly Trautman, *The FDA and Worldwide Quality System Requirements Guidebook for MEDICAL DEVICES*, available through the ASQC Quality Press at (800) 248-1946.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur.

Your response should be directed to the New Jersey Office, FDA, 10 Waterview Blvd., 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District